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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/029,042    05/15/98    KIM

S    003364.P001

HM12/1003  
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EXAMINER
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DEBERRY, R

ART UNIT	PAPER NUMBER
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1647

DATE MAILED:

10/03/01

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/029,042

Applicant(s)

KIM ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Detailed Action***

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647, Regina M. DeBerry.

***Status of Application, Amendments and/or Claims***

A restriction was made 15 June 1999 (Paper No. 5) where claims 1-21 were restricted to the following three groups: expression system/methods of making EPO claims 1-21; expression system/methods of making Factor VIII claims 18-21 and expression system/methods of making TPA claims 18-21. Applicant's election of Group I (claim 1-21, expression system/methods of making EPO) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The amendment filed 11 August 2000 (Paper No. 14) has been entered in full. The amendment filed 20 December 2000 (Paper No. 20) has been entered in full. The amendment filed 19 March 2001 (Paper No. 22) has been entered in full.

The amendment filed 06 August 2001 has been entered in part. A restriction was made 06 August 2001 (Paper No. 26) where claims 1-21 were restricted to following species: Cell type: DE, CEF, QT; Promoter: SV40, HCMV, RSV LTR and Gene Sequence: SY, JM, SH, HE. Applicant's election of Cell type QT, Promoter HCMV MIEP and Gene Sequence SH (SEQ ID NO:5) in Paper No. 27 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-21 are pending and under examination. The amendment filed 06 August 2001 requested amendment to claims 24, 26 and 27. However, since no claims numbered 24, 26 or 27 are present in the application, this requested amendment was not entered.

### ***Sequence Rules***

The specification is not in compliance with 37 CFR 1.821 (d) of the Sequence Rules and Regulations. When the description of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text and claims of the patent application. The specification refers to sequences in Figures 5A-5H, 6 and pages 14 and 15 but does not identify the sequences by their sequence identifiers. Sequences appearing in drawings may be referenced in the drawings themselves or in the corresponding Brief Description thereof. Appropriate correction is required.

### ***Claim Objections***

Claims 2, 5, 6, 8, 11-14, 16, 19, 21 are objected to because of the following informalities: Claims 2, 5, 6, 8, 11-14, 16, 19, 21 encompass non-elected inventions and require amendment to limit to elected invention. Appropriate correction is required.

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 is drawn to the human heterologous protein production system of claim 18, wherein the human heterologous protein is selected from the group consisting of TPA, Factor VIII and EPO. Claim 19 does not further limit the claim of 18 which is drawn to the EPO production system of claim 14, wherein the DNA encoding EPO is selected from the group consisting of SY, JM, SH and HE, respectively described by SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "human heterologous protein production system".  
There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 7, 15 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Donson *et al.* US Patent No. 6,284,492. Claim 1 is drawn to an EPO production system comprising a DNA encoding EPO; a vector for receiving the DNA; and an avian cell for harboring the vector. Claim 7 is drawn to a method for producing EPO comprising the steps of: inserting a DNA encoding an EPO into a vector; transfecting the vector into an avian cell; and culturing the transfected avian cell in media. Claim 15 is drawn to an avian cell as a host for expressing a gene encoding an EPO. Claim 20 is drawn to a method of producing a human heterologous protein comprising the steps of: inserting a DNA encoding a human heterologous protein into a vector; transfecting the vector into an avian cell; and culturing the transfecting avian cell in media. Donson *et al.* describes vectors, avian host cells, the production of various proteins such as EPO, human hemoglobin and methods of making these proteins. Please see reference

including abstract; column 1, lines 29-46; column 2, lines 58-67; column 20, lines 60-67; column 21, lines 1-25; column 51, lines 1-13 and 50-58 and claims.

Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Borden *et al.* US Patent No. 5,968,823. Claim 20 is drawn to a method of producing a human heterologous protein comprising the steps of: inserting a DNA encoding a human heterologous protein into a vector; transfecting the vector into an avian cell; and culturing the transfecting avian cell in media. Borden *et al.* discloses DNA encoding human heterologous proteins, vectors, avian (quail cells, QT-6) and the methods of making the proteins. Please see reference including abstract, column 2, lines 19-44; column 3, lines 42-63 and claims.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 15, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosselman *et al.* US Patent No. 5,162,215. Claim 1 is drawn to an EPO production system comprising a DNA encoding EPO; a vector for receiving the DNA; and an avian cell for harboring the vector. Claim 7 is drawn to a method for producing EPO comprising the steps of: inserting a DNA encoding an EPO into a vector; transfecting the vector into an avian cell; and culturing the transfected avian cell in media. Claim 15 is drawn to an avian cell as a host for expressing a gene encoding an EPO. Claim 20 is drawn to a method of producing a human heterologous protein comprising the steps of: inserting a DNA encoding a human heterologous protein into a vector; transfecting the

vector into an avian cell; and culturing the transfecting avian cell in media. Claim 21 is drawn to the method of claim 20, wherein the human heterologous protein is selected from the group consisting of TPA, Factor VIII and EPO. Bosselman *et al.* describes a production system that includes human EPO DNA, vector, avian host cells and a method of producing the human EPO protein. Please see reference including abstract, column 1, lines 1-26, column 2, lines 62-68; column 3, lines 65-68, column 6, line 8-14 and lines 18-68 and column 7, lines 44-46.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



Claims 2, 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosselman *et al.* US Patent No. 5,162,215 and further in view of Borden *et al.* US Patent No. 5,968,823. Claim 2 is drawn to the EPO production system of claim 1, wherein the avian cell is DE or CEF or QT. Claim 8 is drawn to the method of claim 7, wherein the avian cell is DE or CEF or QT. Claim 16 is drawn to the avian cell of claim 15, wherein the avian cell is DE or CEF or QT. Bosselman *et al.* teaches a production system that includes human EPO DNA, vector, avian host cells and a method of producing the human EPO protein. Bosselman *et al.* does not disclose avian cells which are QT (quail) cells. Borden *et al.* teaches DNA encoding various proteins, vectors, avian (quail cells, QT-6) and the methods of making the proteins. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use avian cells such as QT because they are an accessible established cell line. The person of ordinary skill in the art would have been motivated to make that modification and have expected success because avian cells lines have been used to study various proteins.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD  
September 27, 2001



ELIZABETH KEMMERER  
PRIMARY EXAMINER